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A. SUMMARY OF SAFETY AND EFFECTIVENESS

1. TOXICOLOGY

USP SYSTEMIC INJECTION TEST

Clinical Observations: No toxic signs were observed during the 72 hour observation period.

Weights: All animals gained weight during the test.

Conclusion: This test material met the requirements of the USP Systemic Injection Test, using the extracting media.

2. USP PRIMARY EYE IRRITATION TEST

EYE IRRITATION STUDY: No irritation was observed during the study period.

Clinical Observations: All animals remained healthy throughout the study period.

Conclusion: The test material produced no irritation response in the eyes of the New Zealand rabbits.

B. CYTOTOXICITY - AGAR DIFFUSION

Results: There was no reactivity with the tinted or clear PMMA contact lens buttons.

Conclusion: These samples meet the requirements of USP 23 and ISO 10993-5 for this Cytotoxicity Test.

- C. The spherical contact lens design will have a spherical front and back surface. The base curve (back surface) will contain one or more spherical curves on the periphery of the lens which will have a longer radius of curvature than the central section (optic zone)
- D. The low eccentricity aspheric contact lens will have a spherical front surface and an aspherical back surface (base curve). The eccentricity of the base curve will provide design more closely matching the curvature of the cornea. The design may or may not contain peripheral curves.
- E. Contact lenses were manufactured with a variety of prescriptions to demonstrate they could be manufactured. Rand uses ANSI Z80.2 as a standard for all contact lens tolerances.

F. STATEMENT OF SIMILARITIES AND DIFFERENCES

CLASSIC PMMA

Polymethyl methacrylate  
Lathe cut  
Not gas permeable  
Less than 2% water content  
Index of refraction 1.49  
Hardness 95 (Shore D)

PREDICATE DEVICE

Polymethyl methacrylate and silicone  
Lathe cut  
Not gas permeable  
Less than 2% water content  
Index of refraction 1.49  
Hardness 95 (Shore D)

- G. THE RESULTS OF THE TOXICOLOGY TESTS AND THE FACT THAT PMMA CONTACT LENSES HAVE BEEN MARKETING FOR OVER THIRTY YEARS SHOWS THAT THE PMMA CLASSIC CONTACT LENSES ARE SAFE AND EFFECTIVE FOR THEIR INTENDED USE.